HFI #35 4/10/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

M 803 M

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

April 7, 1997

WL-19-7

Wayne R. Braastad
President/CEO
LifeStyle Hearing, Inc.
6284 E. Grant Rd.
Tucson, AZ 85712

Dear Mr. Braastad:

During an inspection of your manufacturing facility conducted between March 17 and March 18, 1997, our investigator determined that your firm manufactures hearing aids. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, or storage are not in conformance with the Good Manufacturing Practice (GMP) for Medical Device Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and implement sufficient quality assurance procedures to assure that a formally established and documented quality assurance program is performed [21 CFR 820.20]. For example, our investigation determined that your firm has no written procedures to assure that the following quality assurance functions are performed:

   - o review of production records:
   - o approval or rejection of all components;
   - o planned and periodic audits are conducted to verify compliance with the quality assurance program.

2. Failure to prepare and maintain device master record(s) for all models of your hearing aids which include or refer to the location of device specifications, production process specifications, or quality assurance procedures [21 CFR 820.181]. For example, our

investigation disclosed wiring diagrams used to manufacture and test your hearing aids, bear the name of another hearing aid manufacturer.

3. Failure to maintain device history records for all models of your hearing aids which demonstrate that the device is manufactured in accordance with their device master records [21 CFR 820.184]. For example, our investigation disclosed your device history records do not contain any written notations that identify the manufacturing steps or quality assurance checks which are performed to your hearing aids. Additionally, your device history records do not bear any release signatures or dates.

4. Failure to maintain any records of oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device [21 CFR 820.198].

5. Failure to establish and control calibration procedures which include specific directions and limits for accuracy and precision of production and quality assurance measurement equipment [21 CFR 820.61]. For example, our investigation found equipment used in the testing of the performance of your firm's hearing aids past due for calibration.

Additionally, our investigation determined that your user instructional brochure does not contain information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service, as set forth in 21 CFR 801.420(c)(v).

This letter is not intended to be an all-inclusive list of deficiencies at your facility and/or with your devices. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Until it has been determined that corrections are adequate, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending submissions for premarket clearance for devices to which the GMP violations are reasonably related will be cleared. Also, no requests for Certificates For Products For Export will be approved.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. Such actions include, but are not limited to seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific

steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
1990 MacArthur Boulevard
Irvine, California 92612-2445

Sincerely,

for Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Att: Chief Food and Drug Branch
714 "P" Street, Room 440
Sacramento, California 95814